SEP 1 4 2000

K002320

510(k) Summary

Device: Accolade™ C Femoral Component

The Accolade™ C Femoral Component is a neutral, collared femoral stem and is available in a range of sizes to fit varying anatomical requirements. This device is available in two neck angle options, 127° and 132°, for each corresponding body geometry. A distal spacer is offered for use with this femoral component and is offered in various sizes.

This femoral component is intended for the reconstruction of the head and neck of the femoral joint and is intended for implantation with bone cement. The Accolade™ C Femoral Component can be used in conjunction with any currently available Howmedica Osteonics acetabular components, unipolar and bipolar components and Howmedica Osteonics V40™ femoral heads that can be mated with a 5° 40' BG taper.

The Accolade™ C Femoral Component is indicated for cemented primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity. Additionally, this femoral stem can be used in the treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques. This stem is also indicated for use in revision procedures where other treatments or devices have failed.

The Accolade™ C Femoral Component is fabricated from forged cobalt-chromium-molybdenum alloy which complies to ASTM standard F 799. The distal spacer is manufactured from polymethylmethacrylate (PMMA) with BaSO4.

Finite element analysis of this femoral stem indicates the neck strength equals or exceeds the value proposed by Semlitsch, et. al. Body strength of the smallest size stem meets the performance criteria outlined in ISO 7206-8.

The substantial equivalence of the Accolade™ C Femoral Component is based upon equivalence in intended use, materials, design, and operational principles to the Howmedica® DRG Femoral Component (Howmedica Osteonics Corp.; K936126), Howmedica® Premium Femoral Component (Howmedica Osteonics Corp.; K936127), Osteonics® Omnifit® EON™ Hip System (Howmedica Osteonics Corp.; K933561) and Ranawat/Burstein Total Hip Femoral Component (Biomet®; K911685).

For information contact: Ms. Nancy J. Rieder
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Summary Date: July 28, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2000

Ms. Nancy J. Rieder
Rutherford Regulatory Affairs
Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K002320
Trade Name: Accolade C Femoral Component
Regulatory Class: II
Product Code: LZO
Dated: July 28, 2000
Received: July 31, 2000
Amended: September 11, 2000

Dear Ms. Rieder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K002320

Device Name: Accolade™ C Femoral Component

Indications for Use:

The Accolade™ C Femoral Component is indicated for cemented primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity. Additionally, this femoral stem can be used in the treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques. This stem is also indicated for use in revision procedures where other treatments or devices have failed.

The Accolade™ C Femoral Component is intended for implantation with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Vochnes
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002320